

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Sucrose Octanoate Esters

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Esters biodegrade rapidly; are not toxic to mammals and other target organisms; the amount used will not “substantially increase amount of these esters in environment.” TAP pg 5, lines 234-241.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Not persistent; unlikely to interact with other materials used in bee colonies; may adversely impact small arthropods (small or smaller than Varroa mite) in honey bee colony, colony would not be harmed. TAP pg 5, lines 247-254.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Non toxic to honey bees and many beneficial insects. Not phytotoxicity to many crops; biodegrades quickly TAP pg 6, lines 259-268.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		No specific data exist on soil organisms but based upon available data, including the rate of decomposition, no adverse impacts are expected. TAP pg. 6 lines 259-268.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Sucrose, fatty acids carbon dioxide and water are the breakdown products. None are toxic. TAP pg 6, lines 292-293.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		SOEs degrade rapidly and do not resist or accumulate in the environment. TAP pg 6, line 298. This material works as a soap. TAP pg. 2, lines 77-78.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		No subchronic, chronic, immune, endocrine issues have been identified. Estimated ADI for humans is 2.82 lbs/ 176 lb person. Ocular risk exists but unlikely if used according to label. TAP pg 6-7, lines 303-311. This material works as a soap. TAP pg. 2, lines 77-78.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance Sucrose Octanoate Esters

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]			X	
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			No wholly natural product is available for use in honey bee colonies. This material is the only material with EPA approval. Smokes, acetic, formic and lactic acid, sticky boards, screened bottom boards, and drone comb removal have potential for varroa control but none reduce mite levels sufficiently and those that do not require EPA approval (and possible addition to the National List) are not sufficient. TAP pgs 7-8, lines 330-356 and personal knowledge: N. Ostiguy
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]	X			Smokes, acetic, formic and lactic acid, sticky boards, screened bottom boards, and drone comb removal have potential for varroa control but none reduce mite levels sufficiently and those that do not require EPA approval (and possible addition to the National List) are not sufficient. TAP pgs 7-8, lines 330-356 and personal knowledge: N. Ostiguy
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Non-chemical controls are available and new control tactics are being tested. No non-chemical control is sufficient to control mite levels such that colonies will not collapse. TAP pgs 7-8, lines 349-356 and personal knowledge: N. Ostiguy

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance SOE

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			This material degrades rapidly, has very low toxicity, its breakdown products are non-toxic and the use of the material will occur after other non-chemical means of varroa control have failed. TAP pg 5, lines 234-241; is an EPA registered biopesticide, TAP pg 2 line 48.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			The substance has a positive impact on the health of honey bees. This material degrades rapidly, has very low toxicity, its breakdown products are non-toxic and has minimal to no environmental risk. TAP pg 5, lines 230-248 The material increases the long-term viability of organic farms by providing a means to control insect damage with IPM and other tactics fail. This material is consistent with other allowed materials.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?	X			This material is for the treatment of varroa mites in honey bees. Varroa mites vector several lethal viruses in addition to being a parasite.
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: August 2005

Substance: Sucrose Octanoate Esters

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

1. Impact on humans and environment
2. Availability criteria
3. Compatibility & consistency

Criteria Satisfied?

Yes ☐ No ☐ (see B below)

Yes ☐ No ☐ (see B below)

Yes ☐ No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments: _____

C. Proposed Annotation: _____

Basis for annotation: _____

To meet criteria above: _____ Criteria: _____

Other regulatory criteria: _____ Citation: _____

D. Final Board Action & Vote: Motion by: _____ Second: _____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed ¹		Prohibited ²		Handling	
No restriction		Deferred ⁴		Rejected ³	

1—substance voted to be added as “allowed” on National List

Annotation: _____

2—substance to be added to “prohibited” paragraph of National List

Describe why a prohibited substance: _____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

4—substance was recommended to be deferred

Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____

E. Approved by NOSB Chair to transmit to NOP:

Dave Carter, NOSB Chair

Date

F. NOP Action: Include in FR to amend National List: ☐

Return to NOSB ☐ Reason: _____

Richard H. Mathews, Program Manager

Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: August 2005

Substance: Sucrose Octanoate Esters

Committee: Crops ☐ Livestock ☒ Handling ☐

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

1. Impact on humans and environment
2. Availability criteria
3. Compatibility & consistency

Criteria Satisfied?

Yes ☒ No ☐ (see B below)
Yes ☒ No ☐ (see B below)
Yes ☒ No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments: _____

C. Proposed Annotation: Only for use as a miticide in apiculture

Basis for annotation: This is the petitioned use request and the only EPA approved livestock use

To meet criteria above: X Criteria: _____

Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote: Motion by: Michael Lacy

Seconded: Hue Karreman

Vote:

Yes: 4

No: 0

Abstain: 0

Agricultural		Nonagricultural		Crops	
Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock	<input checked="" type="checkbox"/>
Allowed ¹	<input checked="" type="checkbox"/>	Prohibited ²		Handling	
No restriction		Deferred ⁴		Rejected ³	

1—substance voted to be added as “allowed” on National List

Annotation: For addition to 605.603(b) Only for use as a miticide in apiculture

2—substance to be added to “prohibited” paragraph of National List

Describe why a prohibited substance: _____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

4—substance was recommended to be deferred

Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:



Committee Chair

July 12, 2005
Date